REMARKS/ARGUMENTS

Claims 3, 4 and 7-25 are pending. By this Amendment, claims 3, 4, 8, 9, 10, 11 and 12 are amended, and claims 13-25 are added. Reconsideration in view of the above amendments and the following remarks is respectfully requested.

The disclosure was objected to based on informalities. By this Amendment, the priority paragraph has been updated to reflect the patented status of two of the parent applications.

The drawings were objected to since element 11 includes two different descriptors. By this Amendment, the specification has been updated to clarify that the electrode space is part of the interior chamber 11.

Reconsideration and withdrawal of the drawing objection are respectfully requested.

The specification was objected to based on the use means-plus-function in the original claims. By this Amendment, the use of means-plus-function is no longer invoked, thereby obviating the objection.

Reconsideration and withdrawal of the objection are respectfully requested.

Claims 3, 4, 11 and 12 were objected to based on informalities, which have been corrected by this Amendment. In particular, claims 3 and 4 now include punctuation marks and the "means" language in claim 11 has been eliminated. In regard to the rejection of claim 12, Applicant respectfully traverses since claim 12 defines structure and not method in that the drug delivery part of the device is shaped following expansion according to the human epidural space. The phrase "following expansion" defines the structural ability of the drug delivery part to be shaped following expansion, which is structural property.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 3, 7-10 and 12 are rejected under 35 U.S.C. §102(b) over Feiring (U.S. Patent No. 5,236,413). This rejection is respectfully traversed.

Claim 3 is directed to an apparatus for enhanced and controlled delivery of biologically active agent into the spinal structures and/or the brain of a mammal that circumvents the blood brain barrier. The apparatus includes an agent drug delivery device implanted via catheter to the epidural space of the mammal in use. Feiring does not teach or disclose this subject matter. Feiring is directed to a method and apparatus for inducing the permeation of medication into internal tissue, with particular use in blood vessels such as arteries. Column 6, lines 14-16. There is no teaching or disclosure that Feiring discloses an agent drug delivery device implanted via catheter to the epidural space of the mammal in use such that delivery of a biologically active agent is accomplished in a direction from the donor electrode directly into the spinal structures and/or the brain thereby essentially bypassing the blood brain barrier of the mammal, and thereby delivering said biologically active agent to the spinal structures and/or to the brain of the mammal, as set forth in claim 3.

In addition, Feiring does not teach or suggest the subject matter of dependent claims 7-10 and 12. For example, Feiring does not teach or suggest that the donor electrode includes a drug reservoir or drug transfer part for storage of the biologically active agent, an impermeable part that is not involved in the drug transfer, and an electroconductive member (claim 7). Feiring teaches a plurality of pores 30 which appear to extend about the entire periphery of the device, which makes sense since it is intended for use in the arteries. Moreover, Feiring does not teach that the donor electrode includes an impermeable part that controls delivery of the active agent to only a limited circumferential extent of the donor electrode, as set forth in new claim 15. Similarly, Feiring does not teach that the donor electrode includes an expandable drug transfer

surface to allow unidirectional expansion towards the dura mater, as set forth in claim 16. In addition, Feiring does not teach or suggest that the drug transfer part is configured to delivery the agent in a direction from the impermeable part towards a transfer surface of the drug transfer part, as set forth in new dependent claim 17. New dependent claims 18-25 set forth additional structure or features not taught or suggested in Feiring.

In addition, Feiring does not teach or suggest that the donor electrode is expandable thereby allowing the drug reservoir or transfer part to make intimate contact with the dura mater, as set forth in claim 8. In addition, Feiring does not teach or suggest that the donor electrode is configured to be expandable in a direction substantially radial thereby promoting an improved contact interface between the drug reservoir or transfer part and the dura mater (claim 9), or that a conductor of the donor electrode is dynamically movable with an expandable balloon, as set forth in claim 10. In Feiring, the electrode (a wire 36) is wrapped helically about the portion of the shaft 12A that extends through the balloon 14. This is said to enhance uniform radial distribution of the electric field. In an alternative embodiment, the conductive wire may be conducted to one or more metallic band electrodes extending about the shaft within the balloon, for example, as to a mid balloon marker band 38. In addition, the electrode may be in the form of wire mesh within the balloon about the catheter shaft. See column 4, lines 44-64. None of these embodiments teaches or suggests that Feiring's electrode is expandable (claim 8) in a direction substantially radial (claim 9) or is associated with an expandable balloon (claim 10). While the electrode, i.e. conductor 36, is in the form of a wire, metallic band, wire mesh, etc., there is no disclosure that the electrode is dynamically movable with the balloon portion in Feiring.

In addition, Feiring does not teach that the drug delivery device is shaped following expansion according to the human epidural space, as defined in claim 12. The Examiner has apparently ignored the phrase "following expansion", which as explained above defines a physical attribute of the drug delivery device, which attribute is not present in Feiring.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 4 was rejected under 35 U.S.C. §102(b) over Brisken et al. (U.S. Patent No. 5,846,218).

Brisken et al. does not teach or suggest the subject matter of claim 4, which is directed to an apparatus including a drug delivery device implanted via catheter to the epidural space of a mammal in use, a phonophoresis device implanted to the epidural space of the mammal in use, and a power source to deliver a potential gradient so that drug delivery is accomplished to the spinal structures and/or the brain thereby essentially bypassing the blood brain barrier of the mammal, and thereby delivering the biologically active agent to the spinal structures and/or to the brain of the mammal. There is nothing in Brisken et al. (dealing with treatment of coronary and peripheral vasculature) which would suggest its application to the spinal structures and/or the brain, as recited in claim 4.

In addition, Brisken et al. does not teach or suggest that the phonophoresis device includes an impermeable part, a drug transfer part and a piezoelectric transducer between the impermeable part and the drug transfer part, to induce delivery of the biologically active agent in a direction from the impermeable part towards a drug transfer surface of the drug transfer part, as recited in claim 4.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 11 was rejected over Feiring in view of Rosenthal et al. (U.S. Patent No. 6,524,274). This rejection is respectfully traversed as claim 11 depends from claim 3 and is patentable by virtue of that dependency. Rosenthal et al. does not make up for the deficiencies of Feiring, and nor was it relied upon for such.

Reconsideration and withdrawal of the rejection are respectfully requested.

New claims 13-25 are provided for the Examiner's consideration and read on the elected embodiment.

In view of the above amendments and remarks, Applicant respectfully submits that all the claims are patentable and that the entire application is in condition for allowance.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140 under Order No. PTB-4230-7.

Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, he is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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